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Application No. 05 729 744.2 - 1257	Ref. P104047EP/SW	Date 25.07.2008
Applicant Ben Youssef, Oumeima		

Communication under Rule 71(3) EPC

You are informed that the Examining Division intends to grant a European patent on the basis of the above application with the text and drawings as indicated below:

In the text for the Contracting States:

AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IS IT LI LT LU MC NL PL PT RO SE SI SK TR

Description, Pages

1-8 as published

Claims, Numbers

1-13 received on 13.05.2008 with letter of 13.05.2008

Drawings, Sheets

1/6-6/6 as published

With the following amendments to the above-mentioned documents by the examining division

Description, Pages 2,3,7

Claims, Numbers 1-12

Comments

Page 2 amended according to Rule 42(1)(b).

Page 3 amended according to Rule 42(1)(c).

Claim 1 amended according to Rules 43(1)a)-b) and 43(7).
Claims 2,5 and 11 amended according to Rules 43(7) and 49(11).
Claims 3,4,6-10 amended according to Rule 43(7).
Claim 12 amended for clarity, Art. 84.

A copy of the relevant documents is enclosed

The title of the invention in the three official languages of the European Patent Office, the international patent classification, the designated Contracting States, the registered name of the applicant and the bibliographic data are shown on the attached EPO Form 2056.

You are requested within a non-extendable period of **four months** of notification of this communication

1.	to file 1 set of translations of the claim(s) in the two other EPO official languages;		EUR
2a.	to pay the fee for grant including the fee for printing up to and including 35 pages; Reference 007		790.00
2b.	to pay the printing fee for the 36th and each subsequent page; number of pages: 0 Reference 008		0.00
3.	to pay the additional claim fee(s) (R. 71(6) EPC); number of claims fees payable: Reference 016		0.00
	Total amount		790.00

The mention of the grant of the patent shall be published in the European Patent Bulletin as soon as possible after the requirements concerning the translation of the claims and the payment of the fees for grant and printing, claims fees, designation fees and renewal fees as laid down in Rule 71(3), (4), (6) and (8) and (9) EPC are fulfilled.

Any divisional applications relating to this European patent application must be filed directly at the European Patent Office in Munich, The Hague or Berlin in accordance with Article 76(1) and Rule 36 EPC **before** the date on which the European Patent Bulletin mentions the grant of the patent (see Art. 97(3) EPC and OJ EPO 2/2002, 112).

If you do not approve the text intended for grant but wish to request amendments or corrections, the procedure described in Rule 71(4) EPC is to be followed.

If this communication is based upon an auxiliary request, and you reply within the time limit set that you maintain the main or a higher ranking request which is not allowable, the application will be refused (Art. 97(2) EPC).

If the enclosed claims contain amendments proposed by the Examining Division, and you reply within the time limit set that you cannot accept these amendments, refusal of the application under Article 97(2) EPC will result if agreement cannot be reached on the text for grant.

In all cases except those of the previous two paragraphs, if the fees for grant and printing or claims fees are not paid, or the translations are not filed, in due time, the European patent application will be deemed to be withdrawn (R. 71(7) EPC).

For all payments you are requested to use EPO Form 1010 or EPO Form 1010E or to refer to the relevant reference number.

After publication, the European patent specification can be downloaded free of charge from the EPO publication server <https://publications.european-patent-office.org> or ordered from the Vienna sub-office upon payment of a fee (OJ EPO 2005, 126).

Upon request in writing each proprietor will receive the certificate for the European patent **together with one copy** of the patent specification provided that the request is filed within the time limit of Rule 71(3) EPC. If such request has been previously filed, it has to be confirmed within the time limit of Rule 71(3) EPC. The requested copy is free of charge. If the request is filed after expiry of the Rule 71(3) EPC time limit, the certificate will be delivered without a copy of the patent specification (R.74 EPC, Decision of the President of the EPO, Special edition No.3, OJ EPO 2007, D.2).

Note on payment of renewal fees

If a renewal fee falls due between notification of the present communication and the proposed date of publication of the mention of the grant of the European patent, publication will be effected only after the renewal fee and any additional fee have been paid (R. 71(9) EPC).

Under Article 86(2) EPC, the obligation to pay renewal fees to the European Patent Office terminates with the payment of the renewal fee due in respect of the year in which the mention of the grant of the European patent is published.

Filing of translations in the Contracting States

As regards translation requirements prescribed by the Contracting States under Article 65(1) EPC, please consult the website of the European Patent Office

www.epo.org → Patents → Law → Legal texts → National law relating to the EPC

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In case of a valid extension

As regards translation requirements prescribed by the Extension States, please consult the website of the European Patent Office

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Failure to supply a prescribed translation in a Contracting State or an Extension State may result in the patent being deemed to be void *ab initio* in the State concerned (Article 65(3) EPC).

Important note to users of the automatic debiting procedure

The fees for grant and printing and also any additional claims fees due under Rule 71(6) EPC will be debited automatically on the date of filing of the translation of the (relevant) claims, or on the last day of the period of this communication. However, if the designation fees become due as set out in Rule 71(8) EPC and/or a renewal fee becomes due as set out in Rule 71(9) EPC, these should be paid separately by another permitted means of payment in order not to delay the publication of the mention of grant. The same applies in these circumstances to the payment of extension fees. For further details see the Arrangements for the automatic debiting procedure (AAD) and accompanying Information from the EPO concerning the automatic debiting procedure (Annexes A.1 and A.2 to the Arrangements for deposit accounts (ADA) in Supplement to OJ EPO 10/2007).

Examining Division:

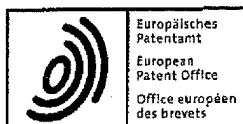
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Enclosure(s): Form 2056
 17 Copies of the relevant documents



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Annex to EPO Form 2004, Communication pursuant to Rule 71(3) EPC

Bibliographical data of European patent application No. 05 729 744.2

For the intended grant of the European patent, the bibliographical data are set out below, for information:

Title of invention:

- Vorrichtung gegen Harninkontinenz
- Urinary incontinence device
- Dispositif pour l'incontinence urinaire

Classification: INV. A61F5/455

Date of filing: 31.03.2005

Priority claimed: GB / 31.03.2004 / GBA0407317

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for which fees have
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*) If the time limit for the payment of designation fees according to Rule 39(1) EPC has not yet expired and the applicant has not withdrawn any designation, **all Contracting States/Extension States** are currently still deemed to be designated. See also Rule 71(8) EPC and, if applicable, the above Note to users of the automatic debiting procedure.

**) If two or more applicants have designated different Contracting States, this is indicated here.

URINARY INCONTINENCE DEVICE

The present invention relates to a female incontinence device, in particular an external incontinence device.

5 Due to the anatomy of the female external urogenital organs, the management of incontinence in female patients has always been difficult both in terms of preventing leakage and acceptability for the patient. There have been a number of devices for female incontinence that attempt to secure an effective seal in a number of ways. Some devices provide an intra vaginal structure to support the device in place.

10 Examples of such devices include those described in US patent 3776235 (Ratcliffe et al), US 3661155 (Linden), US 4198979 (Cooney et al), US 4019498 (Hawtrey et al), US 5785640 (Keresch et al) and UK patent applications GB 2126902A and GB 2090144A. However, such devices have been found to be rigid, uncomfortable, intrusive and still prone to leakage.

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Other devices have used an external adhesive in an attempt to seal the device to the patient's skin and avoid leakage. Examples of such devices include US patent 4822347 (MacDougal) and UK applications GB 2129686A and GB 2193438A.

These devices have also proven to be ineffective in providing an effective seal,

20 particularly with mobile patients.

Further devices include US 4846819 (Welch) which employs a deformable polymer gel ring to provide a seal. The use of a sealing pad of foam plastic material is

described in US patent 3374790 (Mayhorne) but again these devices have been found

25 to be ineffective in preventing leakage.

Other devices provide a contact seal with the patient between the labia minora and labia majora. These devices include US4889533 (Beecher) which includes a pessary for insertion into the vagina to keep the device in place, an elevated side wall around the labia minora and flanges that engage the labia majora. The device requires a flexible crotch panel that is attached to a waistband through straps. Such a device is uncomfortable due to vaginal insertion and engagement of the labia majora.

US3995329 (Williams) describes a hand held urine collection device for use in a standing position designed to be held and pressed against labia majora and has elevated side walls of limited resilience such that when hand pressure is applied by the user the flesh in contact causes abutted flesh to yield to conform to the device to form a seal. The device is not designed for continuous wear and is not suitable for incontinent patients. US5893176 (Magiera et al) describes a hand held device for urine collection whilst in the standing position, the device includes two sealing rings, the interior ring comprises a circumferential wall which engages the exterior of the labia minor and a exterior ring which engages the exterior of the labia majora. The device is intended to be hand held to allow a female user to urinate in a standing position and is not suitable for use in an incontinent person. Such devices include an elevated ring structure to engage the labia minora and an exterior wall or flanges to engage and press on the labia majora to keep the device in place and obtain a contact seal. However, it is found that pressing against the exterior of the labia majora to make a seal is uncomfortable and restrict patient movement and for an active patient such devices are prone to move and rub the patient's skin causing further discomfort.

[A further example of prior art devices is given in US-5053027.]

There remains a need for a female incontinence device that can readily conform to female body shape and can provide an effective seal for both mobile and immobile patients whilst remaining comfortable for the patient without intruding into the vagina, anus, meatus or the exterior of the labia majora.. The present invention

5 overcomes these problems by providing a non-intrusive female incontinence device that utilises a flexible strip which has a substantially flat and smooth face in contact with, and forms a seal about, the female external urogenital organs. Accordingly the present invention provides, a female urinary incontinence device comprising a ^{substantially flat,} flexible strip having an upper face and a lower face, an opening being provided in the strip

10 communicating between the upper and lower faces, the upper face being substantially flat, a fluid collection means affixed to the lower face of the strip in a fluid tight manner around the opening in the strip and outlet for conveying fluid away from the collection means, the device further comprising means for attaching the device to a support means, wherein the strip and opening are sized and shaped such that when it

15 is stretch fitted over the external urogenital organs the labia minora extends through the opening and a fluid tight fit between the upper face of the strip and the flesh surrounding the base of the labia minora is formed, such that in use urine is conveyed from the urethra, through the labia minora, and into the collection means without leakage.

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The flexible strip may be constructed of any suitable material having a degree of elasticity and flexibility to maintain a fluid seal during use. Suitable materials include elastomeric materials such as silicone or latex rubbers. Preferably, the material is hypoallergenic.

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The opening in the strip is preferably of a substantially oval shape to assist in maintaining a seal about the labia minora. The strip in the region of the opening may also have a substantially oval shape.

- 5 The device further comprises a fluid collection means which surrounds the opening on the lower face of the strip in a fluid tight manner. Preferably, at least the portion of the collection means immediately adjacent the lower face is comprised of the same material as the strip. The collection means, or the portion adjacent the lower face and surrounding the opening, can be affixed to the lower face of the device by for example
- 10 heat welding or by an adhesive but preferably it is formed integrally with the strip. In a preferred embodiment, the collection device comprises an oval cup portion surrounding the opening and formed integrally with the strip and of the same material. A second portion of the cup is separated by a thin resilient inner wall also having an opening therein and separating the first portion of the cup from the second portion
- 15 which comprises a hard shell narrowing to an outlet toward its lower end which may be attached to a tube for draining urine or other fluid discharge to a storage vessel for subsequent disposal. The interior wall prevents or reduces backflow of discharged fluid, particularly if the user is in a lying position. In a preferred embodiment the collection means comprises a double walled structure, comprising an inner wall open
- 20 at its lower end and an outer wall spaced from the inner wall so as to define a cavity between the two walls in which any urine that has not been discharged through the drainage outlet provided in the outer wall is collected and prevented from flowing back into the open end of the inner wall.

The device may be in the form of integral incontinence pants. Attachment means such as Velcro fasteners can be provided to allow for positioning of the device. Preferably the device is in a two part form, the first part comprising the strip and collection means provided with connection means for connection to a support means. The connection means may comprise a plurality of straps that can be connected to straps or tensioning means attached to a waistband. Preferably the connection means between the strap portion and the connections on the support means can be adjusted to maintain a positive tension so as provide a force urging the inner face of the strap against the flesh surrounding the labia minora which helps to maintain a fluid tight seal. The strap portion can for example be connected to the support means by a number of elastic straps.

In a preferred embodiment the flexible strip is bifurcated at the front and rear so as to provide a pair of anterior suspension straps and a pair of posterior suspension straps. The straps are connected to a waistband and can be adjusted to provide an optimum degree of tension so as to maintain an effective seal between flat upper face of the flexible strip and the flesh surrounding the labia minora whilst remaining comfortable for the user.

Preferably the device can be disconnected from the support means so that another can be fitted. The device can then be sterilized for reuse which can provide a considerable cost saving over disposable devices.

The device is comfortable for long term wear, it is non-intrusive in that it does not include any internal support structure such as a vaginal or urethral insertion to hold the device in place and it does not rely on exerting pressure against the exterior of the

labia majora to force the labia majora to provide a seal.. The device does not rely on adhesive or contact sensitive areas such as the vaginal or urethral orifice (meatus). The device can be used for permanently immobilised patients but due to the efficient sealing provided by the flexible elastomeric material the device is also suitable for mobile patients. The device is also much easier for hospital staff to change than devices which require vaginal insertion or catheterisation and avoids the possible complications such as infection that can be associated with such procedures. The device can also be used to collect urine from uncooperative patients such as children or those suffering from dementia The device can also be used to collect other vaginal discharge such as experienced during periods and can be used to collect and measure the amount of bleeding give the doctor an indication of the amount of blood loss.

The invention will now be described by way of example with reference to the accompanying drawings in which:

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Figure 1 is a schematic view of a urinary incontinence device according to an embodiment of the invention.

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Figure 2 is an exploded schematic view of the major components of the device of the embodiment shown in Fig 1.

Figure 3 is a schematic of a support harness that can be used in conjunction with the device shown in Figures 1 and 2.

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Figure 4 shows the device of Figure 1 attached to the support harness of Figure 3.

Figure 5 is an exploded schematic view of the device and support harness as worn by a user.

5 Figure 6 shows a device worn by the user and urine collection means.

Referring to Figures 1 and 2, there is shown a urinary incontinence device 13 which comprises a strap part 1 made of a flexible, elastic silicon rubber material, the strap part has a substantially oval central portion 2 having an oval opening 3 therein. A
10 fluid collection part 4 comprises a first cup portion 5 which is formed integrally with the strap part surrounding the opening on the lower face. The first cup portion is about 10mm deep and spaced from the edge of the opening by about 3mm. A second cup part 6 is joined to strip and surrounds the first cup part and is spaced about 10mm from the opening. The second cup part 6 comprises 7 which is formed from the same
15 silicone rubber material as the strip part but is thicker and accordingly more rigid and is spaced from the interior wall so as to define a cavity 24 between the inner and outer walls. The outer cup narrows at its lower end to form a tubular exit 8 that can be connected to drain to an external container. The interior wall⁵ is comprised of a resilient and flexible material the same as the strap part but has relatively thin walls
20 which are shaped so as lie against the labia minora or will tend to collapse in on themselves in parts not in contact with the labia minora. An opening 9 is provided which is in communication with the cavity 24. The strap part divides at the front and the rear to provide anterior support straps 11 and posterior support straps 12. The straps are provided with a plurality of attachment points 19 to allow for adjustment of
25 the device.

Referring to Figures 3 and 4, in use the patient is fitted with a support harness 17 comprising a waistband 14 having front support straps 15 and rear support straps 16 attached to the waistband. The front 11 or rear 12 support straps of the incontinence device can be attached by the attachment points 19 to the corresponding front 15 or rear 16 support straps of the harness by the attachment points 20.

Referring to Figures 5 and 6, in use the device stretch fitted so that the labia minora 30 of the patient passes through the opening 3 in the strip portion and through the opening of the interior wall. When the strip portion is relaxed the base of the labia minora is surrounded by the opening in the strip portion. The labia minora lodge in the interior wall 6 of the cup. The anterior and posterior support straps are then engaged with the corresponding support straps on the harness so as to provide sufficient tension to maintain the flat upper surface of the flexible strip against the flesh surrounding the labia minora. Multiple attachment points are provided so that an optimum tension may be achieved for any user and ensure fluid tight seal is maintained at all times. An effective continuous seal can be maintained from the pubis to beyond the anus. Urine or other fluid exiting through the labia minora passes through the opening 9 of the interior wall and into the cavity 24. The fluid will then drain from the cavity through opening 8 of the exterior wall which is connected via a tube 32 to a collection bag 34. Any fluid not draining through the exit 8 is retained in the cavity 24 and is prevented from draining back through the opening 9 of the inner wall both by the spacing apart of the inner and outer walls and the shaping of the inner wall.

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CLAIMS

1. A non-intrusive female urinary incontinence device (13) comprising a substantially flat, flexible elastic strip (1) having a flat upper face and a lower face, an opening (3) being provided in the strip⁽¹⁾ communicating between the upper and lower faces, a fluid collection means⁽⁴⁾ surrounding⁽⁴⁾ the opening⁽³⁾ in a fluid tight manner on the lower face of the strip⁽¹⁾ and means (19) for attaching the device⁽¹³⁾ to a supporting means (13), *characterized in that the fluid collection means⁽⁴⁾ surrounds⁽⁴⁾ and* wherein the strip⁽¹⁾ and opening⁽³⁾ are sized and shaped such that when it is stretch fitted over the external urogenital organs the labia minora extends through the opening⁽³⁾ and a fluid tight fit between the upper face of the strip⁽¹⁾ and the flesh surrounding the labia minora and around the base of the labia minora is formed, such that in use urine is conveyed from the urethra, through the labia minora, into the collection means⁽⁴⁾ without leakage.
2. A device⁽¹³⁾ according to claim 1 wherein the fluid collection ~~device~~^{means⁽⁴⁾} comprises a funnel portion^(5,6) the curved wall of which at an upper end extends circumferentially from the surface of the oval region around the opening and curves inwards to a lower open end (8) suitable for communicating with a collection vessel (34).
3. A device⁽¹³⁾ according to claim 2 wherein the anterior surface of the wall of said funnel^(5,6) curves more sharply than the posterior surface, such that the lower opening^(5,6) (8) at the base of the funnel^(5,6) lies in a lower plane than that of the opening (3) in the strip⁽¹⁾.

4. A device ⁽¹³⁾ according to claim 2 wherein said funnel ^(5,6) has a double-walled structure, the inner curved wall (5) narrowing symmetrically and more sharply than the outer wall so that an internal opening (9) is formed substantially parallel to and of smaller radius than the opening (3) in the strip.
5. A device ⁽¹³⁾ according to claim 3 or claim 4 wherein a cavity (24) is formed between the posterior surface of the inner ^{curved (5)} wall and the posterior surface of the outer wall ⁽⁶⁾ such that, when the user is in a horizontal position, urine which has passed through the internal opening (9) of the funnel ^(5,6) is prevented from flowing back into the cavity between said opening ⁽³⁾ and the oval opening ⁽³⁾ of the strip ⁽⁴⁾.
6. A device ⁽¹³⁾ according to any of claims 3 to 5 wherein the inner wall (5) and outer wall (6) are spaced apart such that urine in the cavity (24) is prevented from flowing back into the interior opening (9).
7. A device ⁽¹³⁾ according to any of claims 2 to 6 wherein the exterior wall (6) of the funnel ^(5,6) is constructed of resilient flexible material and the interior wall (5) is constructed with substantially the same material as the strip ⁽⁴⁾.
8. A device ⁽¹³⁾ according to any of claims 2 to 7 wherein the funnel ^(5,6) is integral to the strip ⁽⁴⁾.

9. A device⁽¹³⁾ according to any of claims 1 to 8 wherein said strip⁽¹¹⁾ comprises divergent elongated straps^(11,12) at the front and rear to provide anterior and posterior support straps for attachment to a supporting waistband, so that in use the strip is stretched tightly over the external urogenital organs.
- 5 10. A device⁽¹³⁾ according to claim 9 wherein the length of said straps^(11,12) is adjustable with respect to the waistband to allow for differences in size and shape of the user.
- 10 11. A device⁽¹³⁾ according to any preceding claim in which the strip⁽¹¹⁾ portion is capable of being maintained under tension.
12. A urinary incontinence device⁽¹³⁾ further comprising a waistband⁽¹²⁾ and means⁽¹¹⁾ the device of any of claims 1 to 11, ~~the waistband~~ (20) for attachment to the device of any of claims 1 to 11.
- 15 13. A urinary incontinence device according to claim 12, further comprising adjustable attachment means.

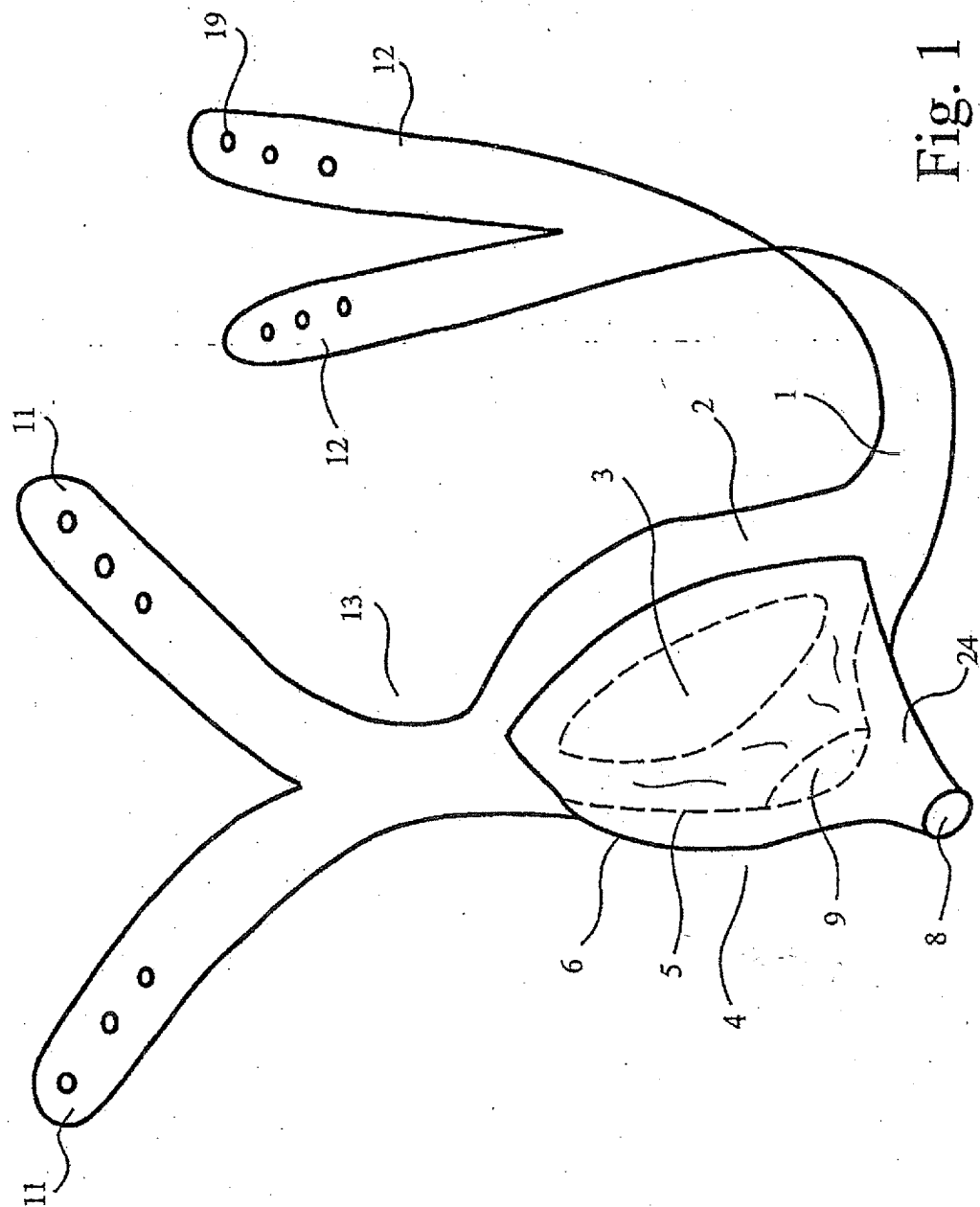
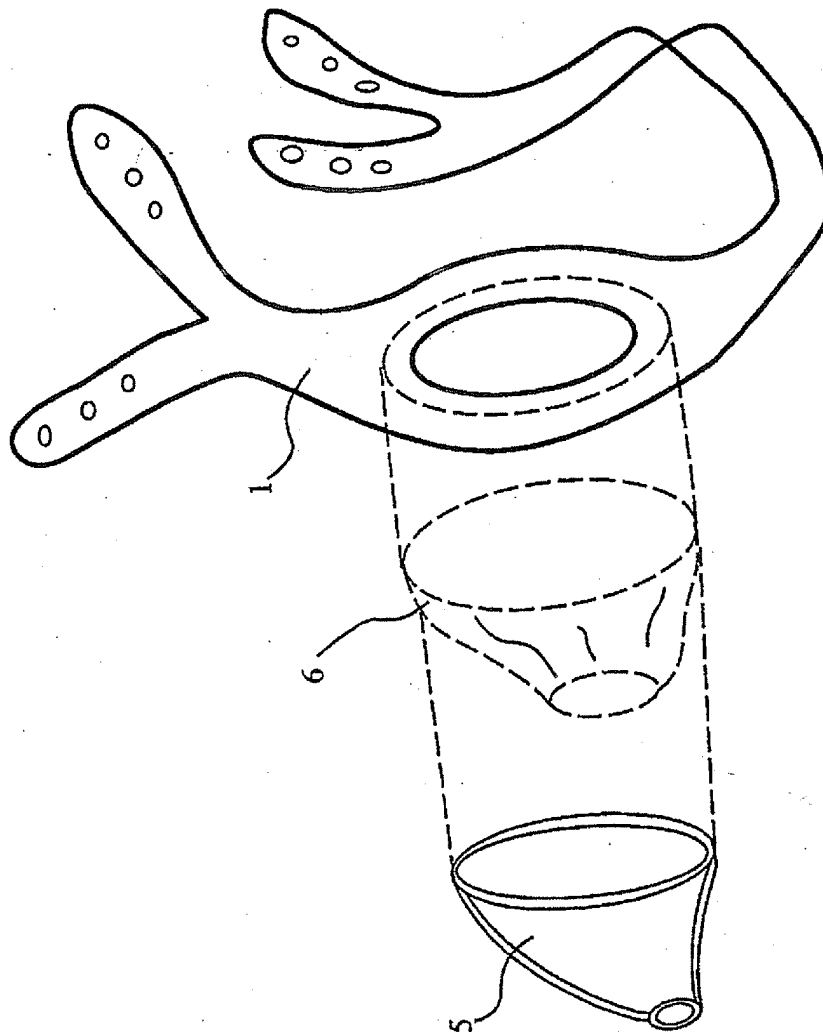


Fig. 1

Fig. 2



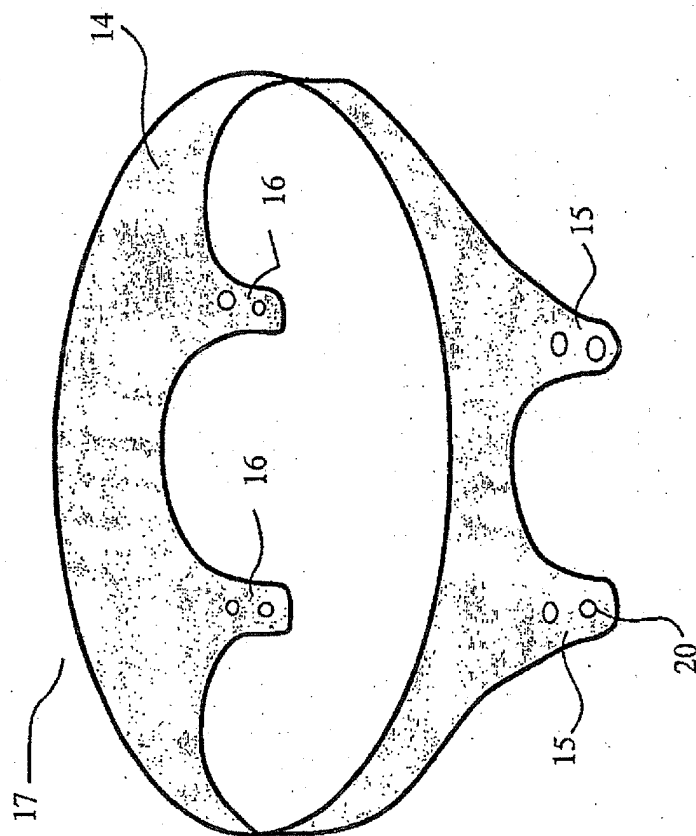


Fig. 3

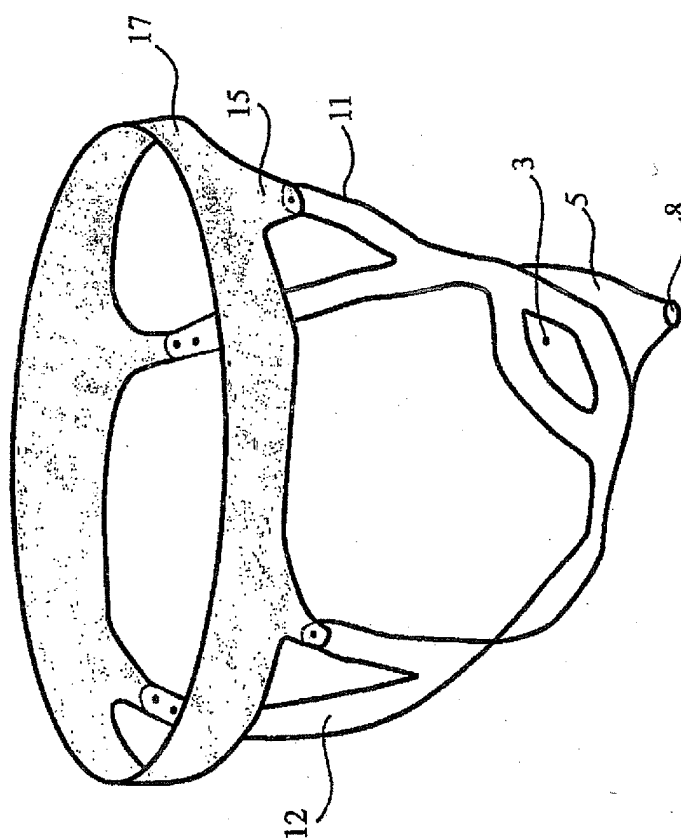


Fig. 4

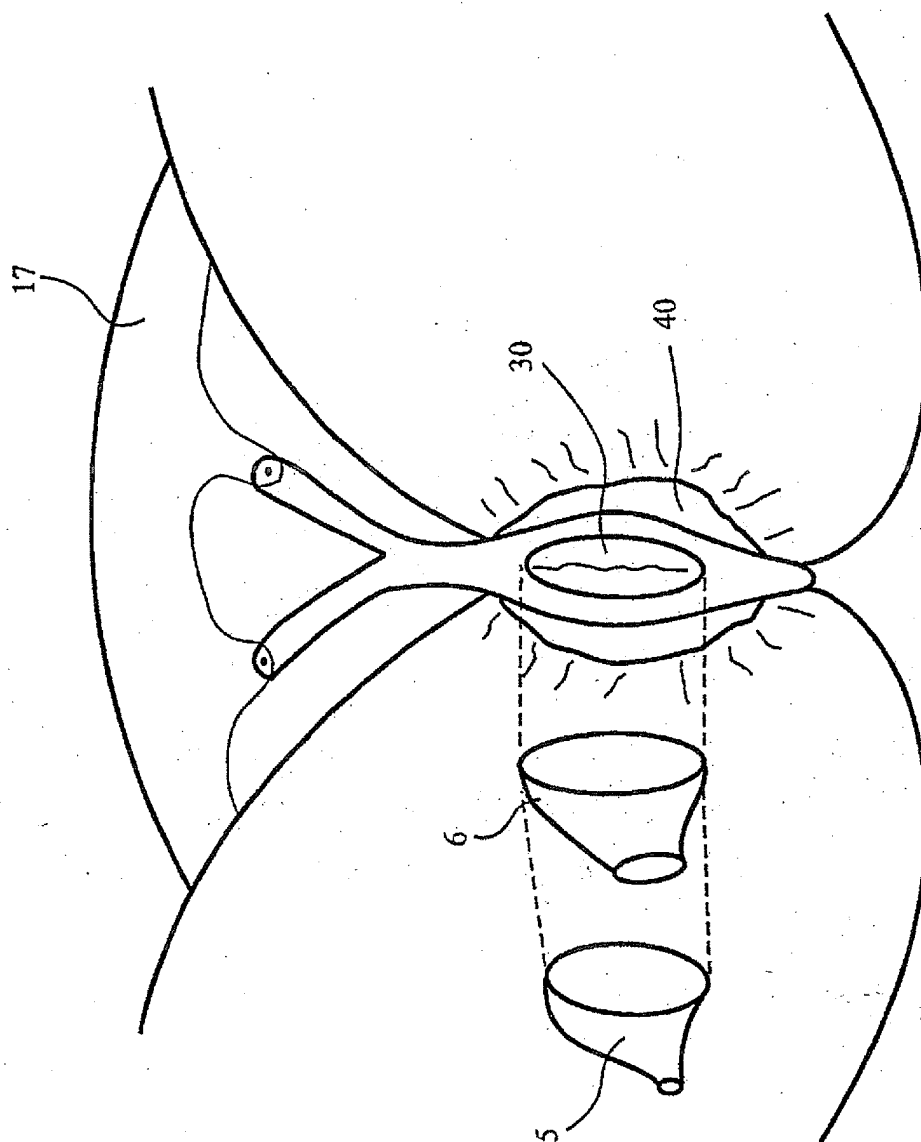


Fig. 5

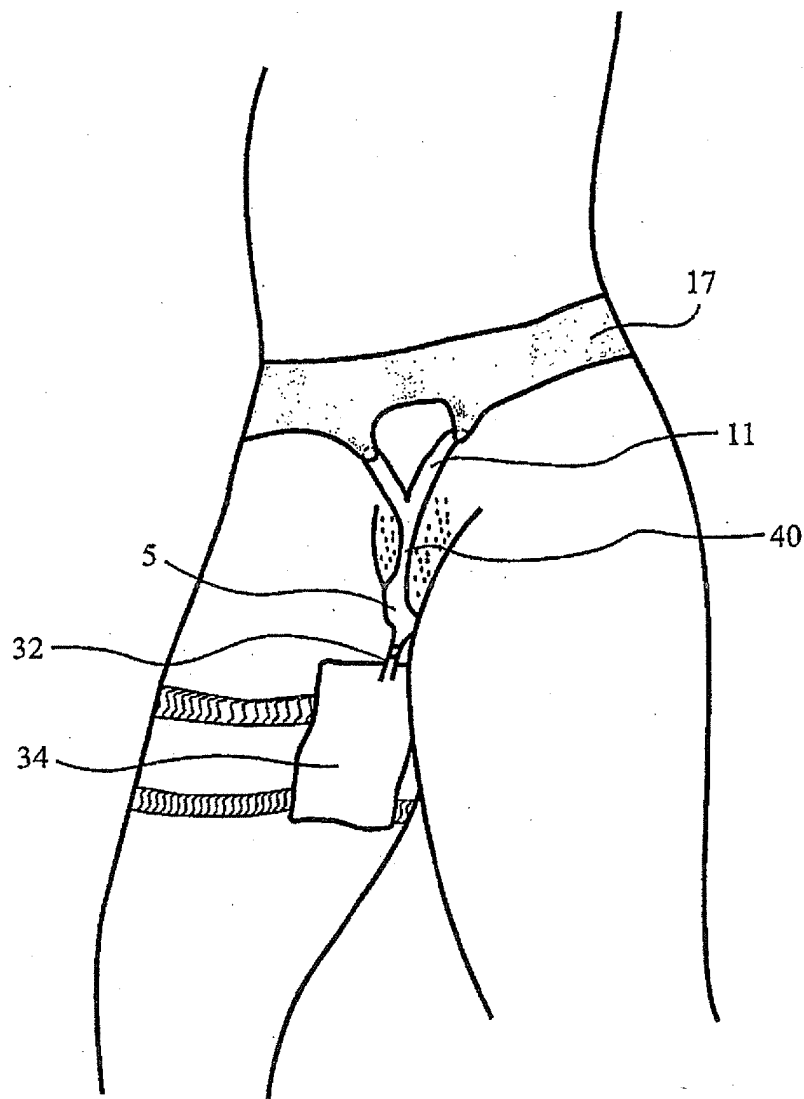


Fig. 6